

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

JOHN L. RUST and KAREN J. RUST	:	Civil Action No. _____
	:	
Plaintiffs	:	
	:	
vs.	:	
	:	
BIOMEDICAL TISSUE SERVICES, LTD., MICHAEL MASTROMARINO, REGENERATION TECHNOLOGIES, INC., and MEDTRONIC SOFAMOR DANEK, USA, INC.	:	Removed from Superior Court for Kent County, Delaware Civil Action No. 06C-12-020 (JTV)
	:	
Defendants.	:	
	:	

NOTICE OF REMOVAL OF ACTION

Defendant, Regeneration Technologies, Inc. ("RTI") appearing solely for the purpose of filing this notice and reserving all rights, defenses, exceptions, objections, and claims and without waiver thereof, and pursuant to 28 U. S. C. §§ 1441 and 1446, hereby removes this action, which has been pending as Case No. 06C-12-020 (JTV) in the Superior Court of Delaware, Kent County, to the United States District Court for the District of Delaware. In support of this notice, RTI states as follows:

1. Plaintiffs John L. Rust and Karen J. Rust filed a Complaint on December 14, 2006 designated Civil Action No. 06C-12-020 in the Superior Court of Delaware, Kent County.
2. Plaintiff's original Complaint contained vague allegations that defendants failed to follow federally mandated protocols, without identifying the protocols. (¶ 15 of Complaint, Exhibit "A").
3. Similar vague allegations appeared in averment 21 indicating that the defendants failed to adhere to government protocol yet the Complaint failed to identify the protocol. (Exhibit "A").

4. As a result, RTI filed a motion pursuant to Delaware Superior Court Rule of Civil Procedure 12(e) for a more definite statement.

5. The purpose of the motion was to address specifically the question of what governmental standards were allegedly violated by RTI.

6. On February 9, 2007, the parties appeared before the Honorable James T. Vaughn for oral argument on RTI's motion.

7. At the conclusion of oral argument the Court indicated that it was inclined to grant the Motion for More Definitive Statement so as to allow RTI to determine if this matter should be removed to Federal Court.

8. Counsel for the plaintiff and RTI then agreed that the Plaintiff would file an Amended Complaint specifically identifying the standards that were allegedly violated.

9. On March 28, 2007, Plaintiff filed an Amended Complaint. (Exhibit B).

10. In the Amended Complaint plaintiff alleges that he underwent a surgical procedure in which his physician implanted in him human tissue that allegedly was improperly procured by Defendant Biomedical Tissue Services, Ltd. and sold by defendants, Regeneration Technologies, Inc. and Medtronic Sofamor Danek USA, Inc. (Exhibit "A") (¶¶9-12 of Amended Complaint, Exhibit "B").

11. Plaintiff's Amended Complaint further alleges that the allograft tissue implanted,

"was implanted into Plaintiff John L. Rust, without following the federally mandated protocols for tissue implementation, failed to implement their own standard operating procedures (SOP's) and failed to screen the tissue for infectious disease. Specifically, Defendants failed to implement their own standard operating procedures for determining donor eligibility as required by 21 C.F.R. 1271, 47(a), failed to review the donor certificate of death for each donor, failed to review relevant medical records of communicable diseases and hospital

admissions for donors as required by 21 C.F.R. 1271, 75(a), failed to review donor eligibility authorizations, failed to establish donor eligibility by confirmation through next of kin, failed to adhere to defendants Donor Medical Social History SOP, and generally operated in violation of their own SOP's, industry standards, AATB guidelines and 21 C.F.R. 1270 and 1271."

12. Similar allegations appear in paragraph 17 of that Amended Complaint in that the allograft tissue implanted into Plaintiff, John L. Rust, was not subjected to federally mandated testing requirements as required under 21 C.F.R. 1270 and 1271 et. seq., 42 U.S.C. 216, 243, 264, 271, et. seq., and Defendants not only failed to adhere to the aforementioned federal guidelines but ignored their own standard operating procedures, industry standards and AATB guidelines.

13. This Court has subject matter jurisdiction over Plaintiff's claims for negligence because the claim is premised on the alleged violation of federal regulation.

14. Furthermore, each of the Plaintiff's claims and remaining claims incorporate by reference the allegations that Defendant violated federal regulations found at 21 C.F.R. 1270-71.

15. In addition to Plaintiff's claims for negligence, this Court has subject matter jurisdiction over all of Plaintiff's remaining allegations in the Amended Complaint because those claims form part of the same case or controversy that gives rise to Plaintiff's claims. 28 U.S.C. § 1367.

16. In so far as this Court has subject matter jurisdiction of this action, removal is proper pursuant to 28 U.S.C. § 1441.

17. Venue is proper under 28 U.S.C. § 587 and 1441(a) because the United States District Court for the District of Delaware is the federal district embracing the Superior Court of Delaware.

18. This notice of removal is timely filed under 28 U.S.C. § 1446(b) because it is filed within 30 days after March 28, 2007, the date when RTI received the Amended Complaint.

19. The other defendants, Biomedical Tissue Service, Ltd. and Michael Mastromarino have not yet been served with the Amended Complaint and need not consent to this request.

20. Pursuant to 28 U.S.C. § 1446(d), RTI has filed this Notice with this Court, is serving a copy of this Notice upon counsel for all parties, and is filing a copy in the Superior Court of Delaware for Kent County.

21. Pursuant to 28 U.S.C. § 1446(a), RTI has attached a copy of "all process. pleadings, and orders served" upon RTI. (Exhibits "A" and "B" .)

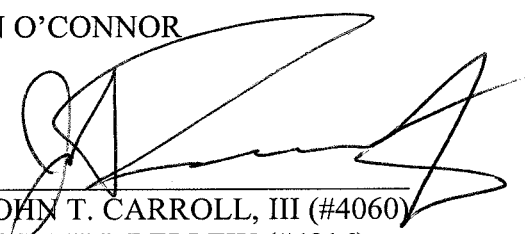
22. RTI reserves the right to submit evidence supporting this Notice of Removal should Plaintiff move to remand.

WHEREFORE, RTI prays that the above-styled action currently pending against it in the Superior Court of Delaware, Kent County be removed to this Court.

Respectfully submitted this 26th day of April, 2007.

COZEN O'CONNOR

BY:



JOHN T. CARROLL, III (#4060)
JOSEPH J. BELLEW (#4816)
Chase Manhattan Centre
1201 North Market Street
Suite 1400
Wilmington, DE 19801
302-295-2000
302-295-2013 Fax
Counsel for Regulation Technologies, Inc.

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing Notice of Removal was served on opposing counsel on the day below noted, via regular first class mail, postage pre-paid addressed as follows:

Brian F. Dolan, Esquire
Stumpf, Vickers & Sandy, P.A.
8 West Market Street
Georgetown, DE 19947

COZEN O'CONNOR

BY: 

JOHN T. CARROLL, III (#4050)

JOSEPH J. BELLEW (#4816)

Chase Manhattan Centre

1201 North Market Street

Suite 1400

Wilmington, DE 19801

302-295-2000

302-295-2013 Fax

Counsel for Regulation Technologies, Inc.

Dated April 26, 2007

EXHIBIT “A”

IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

IN AND FOR KENT COUNTY

JOHN L. RUST and KAREN J. RUST,

Plaintiffs,

vs.

BIOMEDICAL TISSUE SERVICES,
LTD., MICHAEL MASTROMARINO,
REGENERATION TECHNOLOGIES,
INC., and MEDTRONIC SOFAMOR
DANEK, USA, INC.,

Defendants.

: C. A. NO. 06C-12-020 (JTV)

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NON ADR CASE

JURY TRIAL OF TWELVE DEMANDED

COMPLAINT

NOW COMES, the Plaintiffs, John L. Rust and his wife, Karen J. Rust, by and through counsel, Brian F. Dolan, Esquire, Stumpf, Vickers & Sandy, P.A., and do complain of the Defendants as follows:

1. Plaintiffs, John L. Rust and Karen J. Rust, are adult individuals residing together as husband and wife at 411 Cedar Street, Bridgeville, Delaware, 19933.
2. Defendant, Biomedical Tissue Services, Ltd., (hereinafter "Defendant BTS") is a limited liability company organized under the laws of the State of New Jersey, with a principal place of business of 2125 Center Avenue, Suite 300, Fort Lee, New Jersey, 07024. It is believed

that Defendant BTS can be served through its Chief Executive Officer, Defendant Michael Mastromarino.

3. Defendant, Michael Mastromarino, D.D.S., (hereinafter "Defendant Mastromarino") an adult individual, a former dentist or dental surgeon and Chief Executive Officer of Defendant, Biomedical Tissue Services, Ltd., a New Jersey resident whose last known residence is 2125 Center Avenue, Suite 300, Fort Lee, New Jersey, 07024.

4. Defendant, Medtronic Sofamor Danek, USA, Inc., (hereinafter "Defendant Medtronic") is an Indiana corporation with a principal place of business located at 1800 Pyramid Place, Memphis, Tennessee, 38132, and can be served by serving its registered agent, CT Corporation System, 800 South Gay Street, Suite 2021, Knoxville, Tennessee, 37929.

5. Regeneration Technologies, Inc., (hereinafter referred to as "Defendent Regeneration") is a Delaware corporation with a principal place of business located at 11621 Research Circle, Alachua, Florida, 32616, and can be served through its registered agent, United Corporate Services, Inc., 874 Walker Road, Suite C, Dover, Delaware, 19904.

6. At all times relevant heretofore and hereafter, Defendants were engaged, individually and collectively, in harvesting, transporting, distributing, selling or reselling, marketing or otherwise introducing into the stream of interstate commerce, including Delaware, directly or indirectly, individually or through third parties or related entities, human tissue for future transplantation.

7. On or about August 7, 2003, Plaintiff, John L. Rust, was involved in an automobile accident at the intersection of State Road 20 and County Road 431 approximately four miles west of Millsboro, Delaware.

8. As a direct and proximate result of the accident heretofore referred to, Plaintiff, John

L. Rust, sustained multiple injuries, including among others a fractured humerus.

9. Plaintiff, John L. Rust, underwent multiple surgical procedures to repair the fractured humerus. Unfortunately, several of these procedures were unsuccessful. In a follow up procedure performed by Dr. Richard P. DuShuttle on or about December 15, 2004, Dr. DuShuttle removed internal fixation devices, including a intramedullary nail and bone growth stimulator, while implanting an allograft bone with an external fixator on Mr. Rust's arm. The procedure was performed at Bayhealth Medical Center in Dover, Delaware.

10. Plaintiffs believe and therefore aver that the allograft bone utilized by Dr. DuShuttle at Bayhealth Medical Center was provided to Bayhealth through Defendant Medtronic, the distribution partner of Defendant Regeneration Technologies, who has exclusive distribution rights for Defendant Regeneration throughout the United States.

11. Plaintiffs believe and therefore aver that Defendant Regeneration Technologies obtained the tissue utilized in the allograft from Defendant BTS.

12. On or about November 7, 2005, Dr. DuShuttle received notification from representatives at Bayhealth Medical Center that the allograft tissue heretofore referred to which was processed and distributed by Defendant Regeneration may have been obtained as a result of potentially false or inaccurate information received from Defendant BTS regarding donor screening and informed consent records, to wit, an adequate donor eligibility determination may not have been performed by Defendant BTS which potentially may have increased the risk of infectious disease. The relevant infectious communicable diseases included HIV-1, HIV-2, Hepatitis B, Hepatitis C, and Syphilis.

13. Subsequent infectious disease testing performed on Plaintiff, John L. Rust, revealed that he was, in fact, infected with Hepatitis C.

14. Plaintiffs believe and therefore aver that Defendants may have obtained bone graft tissue from cadavers of unknown origin.

15. Plaintiffs believe and therefore aver that Defendants obtained tissue which was implanted into Plaintiff, John L. Rust, without following the federally mandated protocols and without screening for infectious disease.

16. Plaintiffs believe and therefore aver that Defendant BTS by and through Defendant Mastromarino may have altered medical records, death certificates and identities of corpses in order to conceal the identities, lifestyles, medical and disease histories of corpses and as a result, Defendants independently and collectively, jointly and severally, harvested and sold tissue for implementation that originated from people who suffered from infectious diseases, including HIV-1, HIV-2, Hepatitis B, Hepatitis C, and Syphilis.

17. Plaintiffs believe and therefore aver that the allograft tissue implanted into Plaintiff, John L. Rust, was not subjected to federally mandated testing requirements and Defendants cannot confirm that any proper or industry recognized testing has been conducted on the aforementioned tissue.

18. Plaintiffs believe and therefore aver that Defendants individually and collectively, jointly and severally, failed to perform the proper screening of the donor of the tissue that was implanted into Plaintiff.

19. Plaintiffs believe and therefore aver that decedent donors never intended their tissue to be harvested by Defendant BTS by and through Defendant Mastromarino.

20. Plaintiffs believe and therefore aver that in order to circumvent the formal donor and release requirements, Defendant Mastromarino secretly dissected the bodies of tissue donors and prepared them for burial, without knowledge of family members in order to obtain human

tissue which was sold and distributed by Defendant BTS.

21. Plaintiffs believe and therefore aver that in processing and distribution, Defendants failed to adhere to Government protocol and general industry standards protocol for tissue screening which would require blood tests, review of medical records, medical histories, lifestyle screening, interviews with decedent donors' next of kin.

22. Plaintiffs believe and therefore aver that in processing and distribution, Defendants failed to perform serological and microbiological tests to insure that the tissue samples utilized in Plaintiff's bone graft were adequately screened for infectious diseases.

23. Plaintiffs believe and therefore aver that the Defendants transacted business in Delaware, contracted to supply services or things in Delaware, caused tortuous injury in Delaware by acts or omissions inside and outside the State and that Defendants regularly engaged in or solicited business in the state and derived substantial revenue from things consumed in the State to wit, allograft tissue samples.

24. Neither Bayhealth Medical Center nor Plaintiff's surgeon were aware that the tissue implanted into Plaintiff's arm consisted of stolen human tissue or otherwise improperly processed tissue obtained by Defendant BTS and processed and sold by Defendant Regeneration and Defendant Medtronic.

25. The Defendants are not healthcare providers as defined in Title 18, Chapter 68 or as defined under Title 24 although Plaintiffs have nevertheless enclosed herein on Affidavit of Merit pursuant to 18 Del. C. Section 6853.

COUNT I

NEGLIGENCE

26. Plaintiffs restate and incorporate by reference herein their statements and

allegations contained in paragraphs 1 through 25.

27. At all times relevant hereto, Defendants were individually and/or collectively engaged in the business of procuring, harvesting, testing, evaluating, preserving, selling, marketing, labeling, advertising or supplying products from human tissue and bone for implantation in the human body.

28. At all times relevant hereto, Defendants intended the tissue or bone product implanted in Plaintiff, John L. Rust, to be implanted in a living human body.

29. Defendants had a duty to insure that the tissue they supplied to Plaintiff, John L. Rust, was safe for implantation in the human body.

30. Plaintiffs allege that Defendant BTS and Defendant Mastromarino breached their duty by negligently or knowingly dissecting human corpses with known or potential medical conditions or histories which included Syphilis, HIV-1, HIV-2, and Hepatitis or other infectious diseases and that Defendant BTS and Defendant Mastromarino hid the dissection from the family members of the deceased, altered and manipulated legal required documents relating to the donors' consent and the donors' medical condition.

31. Plaintiffs believe and therefore aver that Defendant Regeneration and Defendant Medtronic breached their duty of care in that through the process of inspecting, purchasing, processing and reselling for a transplantation, the tissue and bone they bought from Defendant BTS, Defendants Regeneration and Medtronic either knew, or negligently failed to discover through application of industry standards and/or their own internal criteria for evaluation of donors and harvested human tissue that:

- a) Defendant BTS had illegally harvested the tissue and bone;
- b) Such tissue and bone, because of its origin, in fact, likely came from a person who

suffered from Hepatitis C;

c) Such donor's bone and tissue were not safe or appropriate to use for the production of allografts;

d) Such tissue and/or bone would present an unreasonable danger of harm to the public and individuals similarly situated to Plaintiff, John L. Rust, and cause emotional distress to patients who receive such tainted bone and tissue.

32. Plaintiffs believe and therefore aver that Defendant Regeneration and Defendant Medtronic further breached their duty of care in that they either intentionally, recklessly, or negligently failed to follow internal, industry or government standards or their own criteria in evaluating Defendant BTS donors of raw human tissue and bone by refusing or failing to conduct stringent blood tests, medical records evaluation, medical histories and analysis of coroner reports along with lifestyle screening.

33. Plaintiffs believe and therefore aver that if Defendant Regeneration and Defendant Medtronic had followed their own internal safety guidelines, including the guidelines associated with their Bio-Cleanse process which they actively market to medical professionals, then they would have discovered or known that the donors from which Defendant BTS and Defendant Mastromarino obtained the bone tissue and harvested same from, had never consented to the removal of the bone tissue and that these tissues did not meet the criteria for harvesting, making them inappropriate for processing allografts for use by Plaintiff, John L. Rust, or his physician.

34. Plaintiffs believe and therefore aver that Defendants were at all time relevant hereto negligent, grossly negligent, reckless, willful and wantonly careless in the procurement, harvesting, testing, screening, researching, evaluating, preserving, supplying, marketing, distributing, labeling, advertising and selling of the bone graft material and tissue which was

used in the allograft in Plaintiff.

35. As a direct and proximate result of the negligence heretofore described, Plaintiff was caused to suffer severe physical injury and emotional distress.

36. As a direct and proximate result of the negligent acts of Defendants, the Plaintiff contracted Hepatitis C.

37. As a further direct and proximate result of the negligent acts of Defendants, Plaintiff, John L. Rust, has and will continue to be unable to attend to his usual duties, activities, occupations and hobbies due to his physical incapacities, limitations and disabilities caused by Defendants' negligence.

38. As a further direct and proximate result of the negligent acts of Defendants, Plaintiff, John L. Rust, has incurred medical expenses and will continue to incur medical expenses for the rest of his life.

39. As a further direct and proximate result of the negligence acts of Defendants, Plaintiff, John L. Rust, has suffered lost wages and will continue to suffer from a reduction in his earning capacity for the rest of his life.

WHEREFORE, Plaintiff, John L. Rust, demands that judgment be entered against Defendants and that they be held jointly and severally liable for a full and equitable money award for all of Plaintiff's damages and injuries as may be accorded by law, by the jury or by the Court, including Court costs.

COUNT II

FRAUDULENT MISREPRESENTATION

40. Plaintiffs restate and incorporate by reference herein their statements and allegations contained in paragraphs 1 through 39.

41. Defendants, all or certain of them, made numerous false, misleading and fraudulent representations to the general public and to Plaintiff's healthcare providers, leading Plaintiff's healthcare providers, among others, to believe that Defendants' tissue and bone product was pre-screened, safe, sterile and uncontaminated.

42. Plaintiffs believe and therefore aver that the aforementioned representations were false in that the tissue and bone product supplied by the Defendants were not pre-screened or safe, nor had they successfully passed through the Bio-Cleanse or other appropriate cleansing processes and the use of them had dangerous and potentially life threatening affects and consequences.

43. These representations by Defendants were material, in that if Plaintiff, John L. Rust, and his healthcare providers had known the truth, Plaintiff could have properly been informed of the risk of harm and Plaintiff would not have accepted the product into his body.

44. Defendants, individually or collectively, made these representations knowing them to be false and misleading, and with intent to defraud, mislead and deceive Plaintiff, Plaintiff's healthcare providers and the general public with the intent to induce Plaintiff's healthcare providers and Plaintiff to use Defendants' products.

45. Plaintiff and Plaintiff's healthcare providers acted in reliance upon Defendants' material misrepresentation.

46. As a direct and proximate result of the fraudulent and misleading conduct described herein, Plaintiff was caused to suffer the damages heretofore referred to.

47. In performing the described acts or omissions, Defendants, all or certain of them, acted willfully and wantonly, recklessly, fraudulently, and maliciously towards Plaintiff and others by compromising their safety for the benefit of profit when Defendants, all or certain of

them, had actual knowledge or should have had actual knowledge of the serious potential dangers posed to Plaintiff and others from the contaminated donor tissue.

WHEREFORE, Plaintiff, John L. Rust, demands that judgment be entered against Defendants and that they be held jointly and severally liable for a full and equitable money award for all of Plaintiff's damages and injuries as may be accorded by law, by the jury or by the Court, including Court costs.

COUNT III

BREACH OF WARRANT OF FITNESS

48. Plaintiffs restate and incorporate by reference herein their statements and allegations contained in paragraphs 1 through 47.

49. Defendants were merchants who placed the bone and tissue product utilized in Plaintiff's allograft into the stream of commerce for sale and recommended its use to physicians such as Plaintiff's physician.

50. Defendants had a duty to exercise reasonable care in the harvesting, retrieving, selling, promoting, marketing, labeling, testing, procuring, preserving, inspecting, designing, manufacturing, or distributing human tissue, human bone, human parts and medical products for implantation in the human body, including a duty to:

- a) Insure the product did not cause the user unreasonably dangerous consequences;
- b) Warn of dangerous and potentially fatal risks;
- c) Disclose adverse material facts when making representations to physicians, the Food and Drug Administration (hereinafter "FDA") and the public at large, including the Plaintiff.

51. Plaintiff's physician, the FDA, and Plaintiff had no knowledge of the falsity or incompleteness of the Defendants statements and representations concerning the product at issue.

52. Defendants were under a duty to disclose the defective and unsafe nature of the product at issue to the physicians, the FDA, and to the ultimate consumer such as Plaintiff.

53. By their acts and omissions, Defendants, their agents and employees, expressly warranted to the Plaintiff and Plaintiff's physician that their products were merchantable and fit for the purpose intended and Defendants knew that Plaintiff and his physicians would be relying on this warranty.

54. This warranty was breached because the product at issue was not safe and effective as Defendants had represented.

55. Plaintiff, John L. Rust, was in privity of contract with Defendants in that it was reasonably foreseeable that Plaintiff would be the ultimate consumer of the subject allograft.

56. As a direct and proximate result of Defendants' act and omissions as described herein, Plaintiff, John L. Rust, was caused to suffer severe physical injuries and pain suffering and emotional distress along with financial loss as heretofore described.

WHEREFORE, Plaintiff, John L. Rust, demand that judgment be entered against Defendants and that they be held jointly and severally liable for a full and equitable money award for all of Plaintiff's damages and injuries as may be accorded by law, by the jury or by the Court, including Court costs.

COUNT IV

INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

57. Plaintiffs restate and incorporate by reference herein their statements and allegations contained in paragraphs 1 through 56.

58. Defendants' acts and omissions demonstrate a conduct that was extreme, outrageous, and unnecessarily reckless, a deliberate intent to cause Plaintiff, John L. Rust, and

the general public significant emotional distress, or that can be deemed to be a willful and wanton disregard of the fact that such emotional distress could and should be expected.

59. As a direct and proximate result of the acts and omissions as heretofore described, Plaintiff was caused to suffer and shall be caused in the future to suffer severe personal injuries and severe emotional distress, financial harm, economic loss and medical expenses along with the other damages heretofore described.

WHEREFORE, Plaintiff, John L. Rust, demands that judgment be entered against Defendants and that they be held jointly and severally liable for a full and equitable money award for all of Plaintiff's damages and injuries as may be accorded by law, by the jury or by the Court, including Court costs.

COUNT V

NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

60. Plaintiffs restate and incorporate by reference herein their statements and allegations contained in paragraphs 1 through 59.

61. Defendants' act and omissions demonstrate a conduct that was negligent and this negligence directly and proximately caused Plaintiff severe emotional distress given the nature of the harm caused as described in this Complaint.

62. As a direct and proximate result of Defendants' acts and omissions as described herein, Plaintiff was caused to suffer severe personal injuries, pain and suffering, emotional distress, financial loss, including medical expenses and services along with the other damages heretofore described.

WHEREFORE, Plaintiff, John L. Rust, demands that judgment be entered against Defendants and that they be held jointly and severally liable for a full and equitable money award

for all of Plaintiff's damages and injuries as may be accorded by law, by the jury or by the Court, including Court costs.

COUNT VI

BREACH OF WARRANTY OF MERCHANTABILITY

63. Plaintiffs restate and incorporate by reference herein their statements and allegations contained in paragraphs 1 through 62.

64. Defendants were merchants with respect to the allograft that was implanted in Plaintiff, John L. Rust, and they regularly sold allografts and tissue of the kind implanted in Plaintiff.

65. Defendants' act and omissions breached implied warranties of fitness and merchantability of the product supplied to and implanted in the Plaintiff in that the allograft was not fit for the ordinary purpose for which it was sold.

66. As a direct and proximate result of the acts and omissions as heretofore described, Plaintiff was caused and shall in the future be caused to suffer severe personal injuries, pain and suffering, severe emotional distress and harm, financial or economic loss, including but not limited to obligations for medical services and expenses, present and future lost wages, and other damages as heretofore described.

WHEREFORE, Plaintiff, John L. Rust, demands that judgment be entered against Defendants and that they be held jointly and severally liable for a full and equitable money award for all of Plaintiff's damages and injuries as may be accorded by law, by the jury or by the Court, including Court costs.

COUNT VI

PUNITIVE DAMAGES

67. Plaintiffs restate and incorporate by reference herein their statements and allegations contained in paragraphs 1 through 66.

68. At all times complained of, Defendants acted intentionally or recklessly in the infliction of severe emotional distress and they were certain or substantially certain that such distress would result from their conduct; they knew that the conduct set forth herein was so extreme and outrageous so as to exceed all possible bounds of decency and must be regarded as atrocious, and utterly intolerable in a civilized community; that the actions of Defendants caused the Plaintiff's emotional distress and physical injuries and that the emotional distress suffered by Plaintiff, John L. Rust, along with the nature of the injuries was so severe that no reasonable man or woman could expect to have endured as Plaintiff has.

WHEREFORE, Plaintiffs demand that judgment be entered against Defendants and that they be held jointly and severally liable for a full and equitable money award for all of Plaintiffs' damages and injuries, including punitive, as may be accorded by law, by the jury or by the Court, including Court costs.

COUNT VII

ASSAULT

69. Plaintiffs restate and incorporate by reference herein their statements and allegations contained in paragraphs 1 through 68.

70. As a direct and proximate result of Defendants actions or the actions of their agents through their intentional and/or reckless conduct, and assault on Plaintiff's body as set forth herein, Plaintiff, John L. Rust, has been placed in a reasonable fear of bodily harm as a result of

the implanted human tissue as complained of herein.

WHEREFORE, Plaintiff, John L. Rust, demands that judgment be entered against Defendants and that they be held jointly and severally liable for a full and equitable money award for all of Plaintiff's damages and injuries as may be accorded by law, by the jury or by the Court, including Court costs.

COUNT VIII

BATTERY

71. Plaintiffs restate and incorporate by reference herein their statements and allegations contained in paragraphs 1 through 70.

72. As a direct and proximate result of Defendants and/or their agents and employees' conduct through their intentional and/or reckless conduct as set forth above, the Defendants have committed a battery through actual, unlawful, unauthorized touching without proper informed consent upon Plaintiff's body resulting in the injuries and damages as set forth herein.

WHEREFORE, Plaintiff, John L. Rust, demands that judgment be entered against Defendants and that they be held jointly and severally liable for a full and equitable money award for all of Plaintiff's damages and injuries as may be accorded by law, by the jury or by the Court, including Court costs.

COUNT IX


LOSS OF CONSORTIUM

73. Plaintiffs restate and incorporate by reference herein their statements and allegations contained in paragraphs 1 through 72.


74. The Plaintiff, Karen J. Rust, the wife of Plaintiff, John L. Rust, due to the aforementioned actions of Defendants and as the proximate result of Defendants' negligence and

intentional actions has suffered a loss of companionship, conjugal society, consortium, affection, household services and support of her husband, John L. Rust, much to her great detriment and loss.

WHEREFORE, Plaintiff, Karen J. Rust, demands that judgment against the Defendants as well as holding them jointly and severally liable for a full and equitable money award for all of her damages and injuries as may be accorded by law, by the jury or by the Court, including Court costs.

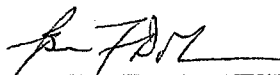


John L. Rust



Karen J. Rust

STUMPF, VICKERS & SANDY, P.A.
8 West Market Street
Georgetown, DE 19947
Attorneys for Plaintiffs

BY: 

Brian F. Dolan
I.D. No. 3190

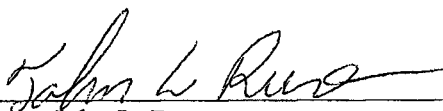
DATED: 12-14-06

STATE OF DELAWARE *

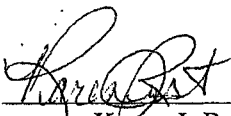
SS

COUNTY OF SUSSEX *

BE IT REMEMBERED that on this 14th day of December,
A.D., 2006, personally appeared before me, the Subscriber, a Notary Public for the State and
County aforesaid, JOHN L. RUST and KAREN J. RUST, who being by me duly qualified
according to law, do depose and say that the facts set forth in the foregoing Complaint are true
and correct.

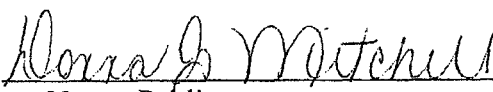


John L. Rust



Karen J. Rust

SWORN TO AND SUBSCRIBED before me the day and year first above written.



Notary Public

IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

IN AND FOR KENT COUNTY

JOHN L. RUST and KAREN J. RUST,

Plaintiffs,

vs.

BIOMEDICAL TISSUE SERVICES,
LTD., MICHAEL MASTROMARINO,
REGENERATION TECHNOLOGIES,
INC., and MEDTRONIC SOFAMOR
DANEK, USA, INC.,

Defendants.

: C. A. NO. 06C-12-020 (JTV)

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NON ADR CASE

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JURY TRIAL OF TWELVE DEMANDED

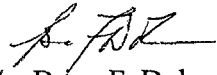
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CERTIFICATION OF VALUE

I, BRIAN F. DOLAN, ESQUIRE, attorney for the Plaintiffs, hereby certifies in good faith at this time that the sum of damages of the Plaintiffs is in excess of \$100,000.00 exclusive of costs and interest.



/s/ Brian F. Dolan

Brian F. Dolan, Esquire

EXHIBIT “B”

IN THE SUPERIOR COURT OF THE STATE OF DELAWARE
IN AND FOR KENT COUNTY

JOHN L. RUST and KAREN J. RUST,	:	C. A. NO. 06C-12-020 (JTV)
	:	
Plaintiffs,	:	
	:	
vs.	:	NON ADR CASE
	:	
BIOMEDICAL TISSUE SERVICES,	:	
LTD., MICHAEL MASTROMARINO,	:	
REGENERATION TECHNOLOGIES,	:	
INC., and MEDTRONIC SOFAMOR	:	JURY TRIAL OF TWELVE DEMANDED
DANEK, USA, INC.,	:	
	:	
Defendants.	:	

AMENDED COMPLAINT
[Amendments are Underlined]

NOW COMES, the Plaintiffs, John L. Rust and his wife, Karen J. Rust, by and through counsel, Brian F. Dolan, Esquire, Stumpf, Vickers & Sandy, P.A., and do complain of the Defendants as follows:

1. Plaintiffs, John L. Rust and Karen J. Rust, are adult individuals residing together as husband and wife at 411 Cedar Street, Bridgeville, Delaware, 19933.
2. Defendant, Biomedical Tissue Services, Ltd., (hereinafter "Defendant BTS") is a limited liability company organized under the laws of the State of New Jersey, with a principal place of business of 2125 Center Avenue, Suite 300, Fort Lee, New Jersey, 07024. At all times relevant, Defendant BTS was registered with the Food and Drug Administration ("FDA") as a

tissue retrieval agency. It is believed that Defendant BTS can be served through its Chief Executive Officer, Defendant Michael Mastromarino.

3. Defendant, Michael Mastromarino, D.D.S., (hereinafter "Defendant Mastromarino") an adult individual, a former dentist or dental surgeon and Chief Executive Officer of Defendant, Biomedical Tissue Services, Ltd., a New Jersey resident whose last known residence is 2125 Center Avenue, Suite 300, Fort Lee, New Jersey, 07024.

4. Defendant Regeneration Technologies, Inc., (hereinafter referred to as "Defendent RTI") is a Delaware corporation with a principal place of business located at 11621 Research Circle, Alachua, Florida, 32616, and can be served through its registered agent, United Corporate Services, Inc., 874 Walker Road, Suite C, Dover, Delaware, 19904. Defendant RTI purchases, processes, distributes, markets and resells processed allograft tissue, including tissue recovered by Defendant BTS. Defendant RTI is licensed by the FDA and is accredited by the American Association of Tissue Banks ("AATB").

5. Defendant, Medtronic Sofamor Danek, USA, Inc., (hereinafter "Defendant Medtronic") is a Tennessee corporation with a principal place of business located at 1800 Pyramid Place, Memphis, Tennessee, 38132, and can be served by serving its registered agent, CT Corporation System, 800 South Gay Street, Suite 2021, Knoxville, Tennessee, 37929.

6. At all times relevant heretofore and hereafter, Defendants were engaged, individually and collectively, in harvesting, transporting, distributing, selling or reselling, marketing or otherwise introducing into the stream of interstate commerce, including Delaware, directly or indirectly, individually or through third parties or related entities, human tissue for future transplantation. Each of the Defendants transacts business in Delaware or derives substantial revenue from the sale of its products in Delaware.

7. On or about August 7, 2003, Plaintiff, John L. Rust, was involved in an automobile accident at the intersection of State Road 20 and County Road 431 approximately four miles west of Millsboro, Delaware.

8. As a direct and proximate result of the accident heretofore referred to, Plaintiff, John L. Rust, sustained multiple injuries, including among others a fractured humerus.

9. Plaintiff, John L. Rust, underwent multiple surgical procedures to repair the fractured humerus. Unfortunately, several of these procedures were unsuccessful. In a follow up procedure performed by Dr. Richard P. DuShuttle on or about December 15, 2004, Dr. DuShuttle removed internal fixation devices, including an intramedullary nail and bone growth stimulator, while implanting an allograft bone with an external fixator on Mr. Rust's arm. The procedure was performed at Bayhealth Medical Center in Dover, Delaware.

10. Plaintiffs believe and therefore aver that the allograft bone utilized by Dr. DuShuttle at Bayhealth Medical Center was provided to Bayhealth through Defendant Medtronic, the distribution partner of Defendant RTI, who has exclusive distribution rights for Defendant RTI throughout the United States.

11. Plaintiffs believe and therefore aver that Defendant RTI obtained the tissue utilized in the allograft from Defendant BTS.

12. On or about November 7, 2005, Dr. DuShuttle received notification from representatives at Bayhealth Medical Center that the allograft tissue heretofore referred to which was processed and distributed by Defendant RTI may have been obtained as a result of potentially false or inaccurate information received from Defendant BTS regarding donor screening and informed consent records, to wit, an adequate donor eligibility determination may not have been performed by Defendant BTS which potentially may have increased the risk of

infectious disease. The relevant infectious communicable diseases included HIV-1, HIV-2, Hepatitis B, Hepatitis C, and Syphilis.

13. Subsequent infectious disease testing performed on Plaintiff, John L. Rust, revealed that he was, in fact, infected with Hepatitis C.

14. Plaintiffs believe and therefore aver that Defendant[] BTS and Defendant Mastromarino obtained bone graft tissue from cadavers of unknown origin. Specifically, Defendant BTS and Defendant improperly and illegally harvested tissue from bodies taken from funeral homes. In order to avoid detection, Defendant BTS and Defendant Mastromarino secretly dissected the bodies before cremation, without consulting the family or next of kin of the decedents. When a funeral was scheduled to be "open casket", harvested bone taken from the deceased was replaced with PVC pipe and other objects so the bodies would still appear normal during the funeral proceedings.

15. Plaintiffs believe and therefore aver that Defendants obtained tissue which was implanted into Plaintiff, John L. Rust, without following the federally mandated protocols for tissue implementation, failed to implement their own standard operating procedures (SOP's) and failed to screen the tissue for infectious disease. Specifically, Defendants failed to implement their own standard operating procedures for determining donor eligibility as required by 21 C.F.R. 1271.47(a), failed to review the certificate of death for each donor, failed to review relevant medical records of communicable diseases and hospital admissions for donors as required by 21 C.F.R. 1271.75(a), failed to review donor eligibility authorizations, failed to establish donor eligibility by confirmation through next of kin, failed to adhere to Defendants Donor Medical Social History SOP, and generally operated in violation of their own SOP's, industry standards, AATB guidelines and 21 C.F.R. 1270 and 1271.

16. Plaintiffs believe and therefore aver that Defendant BTS by and through Defendant Mastromarino may have altered medical records, death certificates and identities of corpses in order to conceal the identities, lifestyles, medical and disease histories of corpses and as a result, Defendants independently and collectively, jointly and severally, harvested and sold tissue for implementation that originated from people who suffered from infectious diseases, including HIV-1, HIV-2, Hepatitis B, Hepatitis C, and Syphilis.

17. Plaintiffs believe and therefore aver that the allograft tissue implanted into Plaintiff, John L. Rust, was not subjected to federally mandated testing requirements as required under 21 C.F.R. 1270 and 1271 et seq., and 42 U.S.C. 216, 243, 264, 271, et seq., and Defendants not only failed to adhere to the aforementioned federal guidelines but ignored their own standard operating procedures, the industry standards and AATB guidelines.

18. Plaintiffs believe and therefore aver that Defendants individually and collectively, jointly and severally, failed to perform the proper screening of the donor of the tissue that was implanted into Plaintiff.

19. Plaintiffs believe and therefore aver that decedent donors never intended their tissue to be harvested by Defendant BTS by and through Defendant Mastromarino.

20. Plaintiffs believe and therefore aver that in order to circumvent the formal donor and release requirements, Defendant Mastromarino secretly dissected the bodies of tissue donors and prepared them for burial, without knowledge of family members in order to obtain human tissue which was sold and distributed by Defendant BTS.

21. Plaintiffs believe and therefore aver that in processing and distribution of the allografts, Defendants failed to adhere to the Government protocols heretofore referred to, general industry standards, AATB guidelines and their own SOP's for tissue screening which

would require blood tests, review of medical records, medical histories, lifestyle screening, and interviews with decedent donors' next of kin.

22. Plaintiffs believe and therefore aver that in processing and distribution, Defendants failed to perform serological and microbiological tests to insure that the tissue samples utilized in Plaintiff's bone graft were adequately screened for infectious diseases.

23. Plaintiffs believe and therefore aver that the Defendants transacted business in Delaware, contracted to supply services or things in Delaware, caused tortuous injury in Delaware by acts or omissions inside and outside the State and that Defendants regularly engaged in or solicited business in the state and derived substantial revenue from things consumed in the State to wit, allograft tissue samples.

24. Neither Bayhealth Medical Center nor Plaintiff's surgeon were aware that the tissue implanted into Plaintiff's arm consisted of stolen human tissue or otherwise improperly processed tissue obtained by Defendant BTS and processed and sold by Defendant RTI and Defendant Medtronic.

25. The Defendants are not healthcare providers as defined in Title 18, Chapter 68 or as defined under Title 24 of the Delaware Code although Plaintiffs have nevertheless enclosed herein an Affidavit of Merit pursuant to 18 Del. C. Section 6853.

COUNT I

NEGLIGENCE

26. Plaintiffs restate and incorporate by reference herein their statements and allegations contained in paragraphs 1 through 25.

27. At all times relevant hereto, Defendants were individually and/or collectively engaged in the business of procuring, harvesting, testing, evaluating, preserving, selling,

marketing, labeling, advertising or supplying products from human tissue and bone for implantation in the human body.

28. At all times relevant hereto, Defendants intended the tissue or bone product implanted in Plaintiff, John L. Rust, to be implanted in a living human body.

29. Defendants had a duty to insure that the tissue they supplied to Plaintiff, John L. Rust, was safe for implantation in the human body.

30. Plaintiffs allege that Defendant BTS and Defendant Mastromarino breached their duty by negligently or knowingly dissecting human corpses with known or potential medical conditions or histories which included Syphilis, HIV-1, HIV-2, and Hepatitis or other infectious diseases and that Defendant BTS and Defendant Mastromarino hid the dissection from the family members of the deceased, altered and manipulated legal required documents relating to the donors' consent and the donors' medical condition.

31. Plaintiffs believe and therefore aver that Defendant RTI, Defendant Medtronic breached their duty of care in that through the process of inspecting, purchasing, processing and reselling for a transplantation, the tissue and bone they bought from Defendant BTS, Defendants RTI, and Medtronic, either knew, or negligently failed to discover through application of federal guidelines, industry standards and/or their own SOP's for evaluation of donors and harvested human tissue that:

- a) Defendant BTS had illegally harvested the tissue and bone;
- b) Such tissue and bone, because of its origin, in fact, likely came from a person who suffered from Hepatitis C;
- c) Such donor's bone and tissue was not safe or appropriate to use for the production of allografts;

d) Such tissue and/or bone would present an unreasonable danger of harm to the public and individuals similarly situated to Plaintiff, John L. Rust, and cause emotional distress to patients who receive such tainted bone and tissue.

32. Plaintiffs believe and therefore aver that Defendant RTI, and Defendant Medtronic, further breached their duty of care in that they either intentionally, recklessly, or negligently:

a) Failed to obtain a proper medical/social history on each donor;

b) Failed to obtain proper authorization from donors, their families and/or next of kin;

c) Failed to comply with 21 C.F.R. 1270, 1271 and 42 U.S.C. §§216, 243, 264, 271, et

seq.;

d) Failed to provide proper warnings of the increased risk of adverse side effects resulting from the transplantation of tissue into Plaintiff;

e) Expressly or impliedly represented the tissue was safe;

f) Failed to conduct medical records reviews;

g) Failed to conduct interviews with next of kin or family members;

h) Failed to conduct a review of the medical examiner's or coroner's report;

i) Failed to obtain and assess laboratory, pathology and radiology reports;

j) Failed to adhere to their own internal SOP's as well as the government standards heretofore described.

33. Plaintiffs believe and therefore aver that if Defendant RTI, and Defendant Medtronic, had followed their own internal SOP's, including the guidelines associated with their Bio-Cleanse process which they actively market to medical professionals, then they would have discovered or known that the donors from which Defendant BTS and Defendant Mastromarino obtained the bone tissue and harvested same from, had never consented to the removal of the

bone tissue and that these tissues did not meet the criteria for harvesting, making them inappropriate for processing allografts for use by Plaintiff, John L. Rust, or his physician.

34. Plaintiffs believe and therefore aver that Defendants were at all time relevant hereto negligent, grossly negligent, reckless, willful and wantonly careless in the procurement, harvesting, testing, screening, researching, evaluating, preserving, supplying, marketing, distributing, labeling, advertising and selling of the bone graft material and tissue which was used in the allograft in Plaintiff.

35. As a direct and proximate result of the negligence heretofore described, Plaintiff was caused to suffer severe physical injury and emotional distress.

36. As a direct and proximate result of the negligent acts of Defendants, the Plaintiff contracted Hepatitis C.

37. As a further direct and proximate result of the negligent acts of Defendants, Plaintiff, John L. Rust, has and will continue to be unable to attend to his usual duties, activities, occupations and hobbies due to his physical incapacities, limitations and disabilities caused by Defendants' negligence.

38. As a further direct and proximate result of the negligent acts of Defendants, Plaintiff, John L. Rust, has incurred medical expenses and will continue to incur medical expenses for the rest of his life.

39. As a further direct and proximate result of the negligence acts of Defendants, Plaintiff, John L. Rust, has suffered lost wages and will continue to suffer from a reduction in his earning capacity for the rest of his life.

WHEREFORE, Plaintiff, John L. Rust, demands that judgment be entered against Defendants and that they be held jointly and severally liable for a full and equitable money

award for all of Plaintiff's damages and injuries as may be accorded by law, by the jury or by the Court, including Court costs.

COUNT II

FRAUDULENT MISREPRESENTATION

40. Plaintiffs restate and incorporate by reference herein their statements and allegations contained in paragraphs 1 through 39.

41. Defendants, all or certain of them, made numerous false, misleading and fraudulent representations to the general public and to Plaintiff's healthcare providers, leading Plaintiff's healthcare providers, among others, to believe that Defendants' tissue and bone product was pre-screened, safe, sterile, uncontaminated, and harvested from consenting donors. Defendants also failed to disclose this material information regarding the tissue grafts placed into the stream of commerce and which were subsequently implanted into Plaintiff, John Rust.

42. Plaintiffs believe and therefore aver that the aforementioned representations were false in that the tissue and bone product supplied by the Defendants were not pre-screened or safe, nor had they successfully passed through the Bio-Cleanse or other appropriate cleansing processes and the use of them had dangerous and potentially life threatening affects and consequences.

43. These representations by Defendants were material, in that if Plaintiff, John L. Rust, and his healthcare providers had known the truth, Plaintiff could have properly been informed of the risk of harm and Plaintiff would not have accepted the product into his body.

44. Defendants, individually or collectively, made these representations knowing them to be false and misleading, and with intent to defraud, mislead and deceive Plaintiff, Plaintiff's healthcare providers and the general public with the intent to induce Plaintiff's healthcare

providers and Plaintiff to use Defendants' products.

45. Plaintiff and Plaintiff's healthcare providers acted in reliance upon Defendants' material misrepresentation.

46. As a direct and proximate result of the fraudulent and misleading conduct described herein, Plaintiff was caused to suffer the damages heretofore referred to.

47. In performing the described acts or omissions, Defendants, all or certain of them, acted willfully and wantonly, recklessly, fraudulently, and maliciously towards Plaintiff and others by compromising their safety for the benefit of profit when Defendants, all or certain of them, had actual knowledge or should have had actual knowledge of the serious potential dangers posed to Plaintiff and others from the contaminated donor tissue.

WHEREFORE, Plaintiff, John L. Rust, demands that judgment be entered against Defendants and that they be held jointly and severally liable for a full and equitable money award for all of Plaintiff's damages and injuries as may be accorded by law, by the jury or by the Court, including Court costs.

COUNT III

BREACH OF EXPRESS WARRANTY OF FITNESS

48. Plaintiffs restate and incorporate by reference herein their statements and allegations contained in paragraphs 1 through 47.

49. Defendants were merchants who placed the bone and tissue product utilized in Plaintiff's allograft into the stream of commerce for sale and recommended its use to physicians such as Plaintiff's physician.

50. Defendants had a duty to exercise reasonable care in the harvesting, retrieving, selling, promoting, marketing, labeling, testing, procuring, preserving, inspecting, designing,

manufacturing, or distributing human tissue, human bone, human parts and medical products for implantation in the human body, including a duty to:

- a) Insure the product did not cause the user unreasonably dangerous consequences;
- b) Warn of dangerous and potentially fatal risks;
- c) Disclose adverse material facts when making representations to physicians, the Food and Drug Administration (hereinafter "FDA") and the public at large, including the Plaintiff.

51. Plaintiff's physician, the FDA, and Plaintiff had no knowledge of the falsity or incompleteness of the Defendants statements and representations concerning the product at issue.

52. Defendants were under a duty to disclose the defective and unsafe nature of the product at issue to the physicians, the FDA, and to the ultimate consumer such as Plaintiff.

53. By their acts and omissions, Defendants, their agents and employees, expressly warranted to the Plaintiff and Plaintiff's physician that their products were merchantable and fit for the purpose intended and Defendants knew that Plaintiff and his physicians would be relying on this warranty.

54. This warranty was breached because the product at issue was not safe and effective as Defendants had represented and Plaintiff was injured.

55. Plaintiff, John L. Rust, was in privity of contract with Defendants in that it was reasonably foreseeable that Plaintiff would be the ultimate consumer of the subject allograft.

56. As a direct and proximate result of Defendants' act and omissions as described herein, Plaintiff, John L. Rust, was caused to suffer severe physical injuries and pain suffering and emotional distress along with financial loss as heretofore described.

WHEREFORE, Plaintiff, John L. Rust, demand that judgment be entered against Defendants and that they be held jointly and severally liable for a full and equitable money

award for all of Plaintiff's damages and injuries as may be accorded by law, by the jury or by the Court, including Court costs.

COUNT IV

INTENTIONAL INFLECTION OF EMOTIONAL DISTRESS

57. Plaintiffs restate and incorporate by reference herein their statements and allegations contained in paragraphs 1 through 56.

58. Defendants' acts and omissions demonstrate a conduct that was extreme, outrageous, and unnecessarily reckless, in a deliberate intent to cause Plaintiff, John L. Rust, and the general public significant emotional distress, or that can be deemed to be a willful and wanton disregard of the fact that such emotional distress could and should be expected.

59. As a direct and proximate result of the acts and omissions as heretofore described, Plaintiff was caused to suffer and shall be caused in the future to suffer severe personal injuries and severe emotional distress, financial harm, economic loss and medical expenses along with the other damages heretofore described.

WHEREFORE, Plaintiff, John L. Rust, demands that judgment be entered against Defendants and that they be held jointly and severally liable for a full and equitable money award for all of Plaintiff's damages and injuries as may be accorded by law, by the jury or by the Court, including Court costs.

COUNT V

NEGLIGENT INFLECTION OF EMOTIONAL DISTRESS

60. Plaintiffs restate and incorporate by reference herein their statements and allegations contained in paragraphs 1 through 59.

61. Defendants' act and omissions demonstrate a conduct that was negligent and this

negligence directly and proximately caused Plaintiff severe emotional distress given the nature of the harm caused as described in this Complaint.

62. As a direct and proximate result of Defendants' acts and omissions as described herein, Plaintiff was caused to suffer severe personal injuries, pain and suffering, emotional distress, financial loss, including medical expenses and services along with the other damages heretofore described.

WHEREFORE, Plaintiff, John L. Rust, demands that judgment be entered against Defendants and that they be held jointly and severally liable for a full and equitable money award for all of Plaintiff's damages and injuries as may be accorded by law, by the jury or by the Court, including Court costs.

COUNT VI

BREACH OF WARRANTY OF MERCHANTABILITY

63. Plaintiffs restate and incorporate by reference herein their statements and allegations contained in paragraphs 1 through 62.

64. Defendants were merchants with respect to the allograft that was implanted in Plaintiff, John L. Rust, and they regularly sold allografts and tissue of the kind implanted in Plaintiff and such allografts carried with them the implied warranty of merchantability. Plaintiff's allege that this implied warranty included that the body parts were safe and non-defective for their intended use. As applied to transplantable human tissues and bones, such warranty included a warranty of reasonable safe protection from infectious diseases and that the human tissue was obtained through legal means.

65. Defendants' act and omissions breached these implied warranties of fitness and

merchantability of the product supplied to and implanted in the Plaintiff in that the allograft was not fit for the ordinary purpose for which it was sold, was not free from infectious disease, and was not obtained legally.

66. Defendants failed to exercise good faith in determining the process of safety related defects in their product.

67. None of the above-mentioned warranties have been effectively disclaimed by any Defendant in this action.

68. Defendants are liable for breach of implied warranty of merchantability as set forth above.

69. As a direct and proximate result of the acts and omissions as heretofore described, Plaintiff was caused and shall in the future be caused to suffer severe personal injuries, pain and suffering, severe emotional distress and harm, financial or economic loss, including but not limited to obligations for medical services and expenses, present and future lost wages, and other damages as heretofore described.

WHEREFORE, Plaintiff, John L. Rust, demands that judgment be entered against Defendants and that they be held jointly and severally liable for a full and equitable money award for all of Plaintiff's damages and injuries as may be accorded by law, by the jury or by the Court, including Court costs.

COUNT VI

PUNITIVE DAMAGES

70. Plaintiffs restate and incorporate by reference herein their statements and allegations contained in paragraphs 1 through 69.

71. At all times complained of, Defendants acted intentionally or recklessly in the infliction of severe emotional distress and they were certain or substantially certain that such distress would result from their conduct; they knew that the conduct set forth herein was so extreme and outrageous so as to exceed all possible bounds of decency and must be regarded as atrocious, and utterly intolerable in a civilized community; that the actions of Defendants caused the Plaintiff's emotional distress and physical injuries and that the emotional distress suffered by Plaintiff, John L. Rust, along with the nature of the injuries was so severe that no reasonable man or woman could expect to have endured as Plaintiff has.

WHEREFORE, Plaintiffs demand that judgment be entered against Defendants and that they be held jointly and severally liable for a full and equitable money award for all of Plaintiffs' damages and injuries, including punitive, as may be accorded by law, by the jury or by the Court, including Court costs.

COUNT VII

ASSAULT

72. Plaintiffs restate and incorporate by reference herein their statements and allegations contained in paragraphs 1 through 71.

73. As a direct and proximate result of Defendants actions or the actions of their agents through their intentional and/or reckless conduct, and assault on Plaintiff's body as set forth herein, Plaintiff, John L. Rust, has been placed in a reasonable fear of bodily harm as a result of the implanted human tissue as complained of herein.

WHEREFORE, Plaintiff, John L. Rust, demands that judgment be entered against Defendants and that they be held jointly and severally liable for a full and equitable money award for all of Plaintiff's damages and injuries as may be accorded by law, by the jury or by the

Court, including Court costs.

COUNT VIII

BATTERY

74. Plaintiffs restate and incorporate by reference herein their statements and allegations contained in paragraphs 1 through 73.

75. As a direct and proximate result of Defendants and/or their agents and employees' conduct through their intentional and/or reckless conduct as set forth above, the Defendants have committed a battery through actual, unlawful, unauthorized touching without proper informed consent upon Plaintiff's body resulting in the injuries and damages as set forth herein.

WHEREFORE, Plaintiff, John L. Rust, demands that judgment be entered against Defendants and that they be held jointly and severally liable for a full and equitable money award for all of Plaintiff's damages and injuries as may be accorded by law, by the jury or by the Court, including Court costs.

COUNT IX

LOSS OF CONSORTIUM

76. Plaintiffs restate and incorporate by reference herein their statements and allegations contained in paragraphs 1 through 75.

77. The Plaintiff, Karen J. Rust, the wife of Plaintiff, John L. Rust, due to the aforementioned actions of Defendants and as the proximate result of Defendants' negligence and intentional actions has suffered a loss of companionship, conjugal society, consortium, affection, household services and support of her husband, John L. Rust, much to her great detriment and loss.

WHEREFORE, Plaintiff, Karen J. Rust, demands that judgment against the Defendants

as well as holding them jointly and severally liable for a full and equitable money award for all of her damages and injuries as may be accorded by law, by the jury or by the Court, including Court costs.

STUMPF, VICKERS & SANDY, P.A.
8 West Market Street
Georgetown, DE 19947
Attorneys for Plaintiffs

BY: /s/ Brian F. Dolan

Brian F. Dolan
I.D. No. 3190

DATED: March 28, 2007

JS 44 (Rev. 11/04)

CIVIL COVER SHEET

The JS-44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THIS FORM.)

I (a) PLAINTIFFS

JOHN L. RUST AND KAREN J. RUST

(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF
(EXCEPT IN U.S. PLAINTIFF CASES)

SUSSEX COUNTY DELAWARE

DEFENDANTS

BIOMEDICAL TISSUE SERVICES, LTD.; MICHAEL MASTRO;
REGENERATION TECHNOLOGIES, INC.; AND MEDTRONIC SOFAMORE
DANEK, USA, INC.COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT
(IN U.S. PLAINTIFF CASES ONLY)

BERGEN COUNTY NEW JERSEY

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE
TRACT OF LAND INVOLVED

(c) ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER)

BRIAN F. DOLAN
STUMPF VICKERS AND SANDY
8 WEST MARKET STREET
GEORGETOWN, DE 19947
302) 856-3561

ATTORNEYS (IF KNOWN)

JOHN T. CARROLL, III, (DE NO. 4060)
JOSEPH J. BELLEW (DE NO. 4816)
1201 N. MARKET STREET, SUITE 1400
WILMINGTON, DE 19801
(302) 295-2000

07 - 222

II. BASIS OF JURISDICTION

(PLACE AN X IN ONE BOX ONLY)

☐ 1 U.S. GOVERNMENT
Plaintiff☒ 3 FEDERAL QUESTION
(U.S. Government Not a Party)☐ 2 U.S. GOVERNMENT
Defendant☐ 4 DIVERSITY
(Indicate Citizenship of
Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES

(For Diversity Cases Only)

(PLACE AN X IN ONE BOX

FOR PLAINTIFF AND ONE BOX FOR DEFENDANT)

Citizen of This State

☐ 1PTF DEF
☐ 1

Citizen of Another State

☐ 2☐ 2Citizen or Subject of a
Foreign Country☐ 3☐ 3Incorporated or Principal Place
of Business in This State☐ 4☐ 4Incorporated and Principal Place
of Business in Another State☐ 5☐ 5

Foreign Nation

☐ 6☐ 6

V. NATURE OF SUIT (PLACE AN X IN ONE BOX ONLY)

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury	PERSONAL INJURY <input checked="" type="checkbox"/> 362 Personal Injury-- Med Malpractice <input type="checkbox"/> 365 Personal Injury-- Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 610 Agriculture <input type="checkbox"/> 620 Other Food & Drug <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 630 Liquor Laws <input type="checkbox"/> 640 R.R. & Truck <input type="checkbox"/> 650 Airline Regs <input type="checkbox"/> 660 Occupational Safety/Health <input type="checkbox"/> 690 Other LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 730 Labor/Mgmt. Reporting & Disclosure Act <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Rel. Inc Security Act	<input type="checkbox"/> 422 Appeal <input type="checkbox"/> 28 USC 158 <input type="checkbox"/> 423 Withdrawal <input type="checkbox"/> 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS--Third Party 26 USC 7809	<input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce/ICC Rates/etc. <input type="checkbox"/> 480 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 810 Selective Service <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 875 Customer Challenge 12 USC 3410 <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 892 Economic Stabilization <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 894 Energy Allocation Act <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 900 Appeal of Fee Determination Under Equal Access to Justice <input type="checkbox"/> 950 Constitutionality of State Statutes <input type="checkbox"/> 890 Other Statutory Actions (Warsaw Convention)
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 444 Welfare <input type="checkbox"/> 440 Other Civil Rights	PRISONER PETITIONS <input type="checkbox"/> 510 Motions to Vacate Sentence Habeas Corpus: <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Other			

IV. ORIGIN

(PLACE AND X IN ONE BOX ONLY)

☐ 1 Original
Proceeding☒ Removed from
State Court☐ 3 Remanded from
Appellate Court☐ 4 Reinstated or
Reopened☐ 5 Transferred from
another district
(specify)☐ 6 Multidistrict
Litigation☐ 7 Appeal to District
Judge from
Magistrate
Judgment

VI. CAUSE OF ACTION

(CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE.

(DO NOT CITE JURISDICTIONAL STATUTES UNLESS DIVERSITY):

28 U.S.C. §§1441 AND 1446

BRIEF DESCRIPTION OF CAUSE: PERSONAL INJURY DAMAGES AS MORE FULLY SET FORTH IN THE COMPLAINT

VII. REQUESTED IN
COMPLAINT:CHECK IF THIS IS A
☐ UNDER F.R.C.P. 23

CLASS ACTION

DEMAND

Check YES only if demanded in complaint:

JURY DEMAND: YES

NO

VIII. RELATED CASE(S)
IF ANY None

(See instructions):

JUDGE

DOCKET NUMBER

DATE
APRIL 26, 2007

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT #

AMOUNT

APPLYING IFP

MAG. JUDGE

AO FORM 85 RECEIPT (REV. 9/04)

United States District Court for the District of Delaware

Civil Action No. 07 - 222

ACKNOWLEDGMENT
OF RECEIPT FOR AO FORM 85

NOTICE OF AVAILABILITY OF A
UNITED STATES MAGISTRATE JUDGE
TO EXERCISE JURISDICTION

I HEREBY ACKNOWLEDGE RECEIPT OF 4 COPIES OF AO FORM 85.

4/26/07

(Date forms issued)

Jeffrey E. Mitchell
(Signature of Party or their Representative)

JEFFREY E. MITCHELL
(Printed name of Party or their Representative)

Note: Completed receipt will be filed in the Civil Action